

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

CURIA IP HOLDINGS, LLC,

Plaintiff,

v.

SALIX PHARMACEUTICALS, LTD.;  
SALIX PHARMACEUTICALS, INC.;  
BAUSCH HEALTH COMPANIES INC.;  
ALFASIGMA S.P.A.; and  
ALFASIGMA USA, INC.,

Defendants.

Civil Action No. 21-19293 (ES) (JRA)  
(CONSOLIDATED)

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**DEFENDANTS' OPENING CLAIM  
CONSTRUCTION BRIEF ('099 PATENT)**

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## I. INTRODUCTION

Defendants Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., Bausch Health Companies Inc., Alfasigma S.P.A., and Alfasigma USA, Inc. (collectively, “Defendants”), respectfully submit this opening claim construction brief concerning U.S. Patent No. 11,739,099 (“the ’099 Patent”).

This is the second round of claim construction in these consolidated cases. In the first round, the Court construed claims of the four patents asserted in the first case: U.S. Patent Nos. 9,186,355 (the “’355 Patent”); 10,556,915 (the “’915 Patent”); 10,745,415 (the “’415 Patent”); and 10,961,257 (the “’257 Patent”). The Court’s claim construction Opinion as to these patents, ECF No. 210, issued on January 26, 2024 (“*Markman* Opinion I”). Ex. 1.<sup>1</sup>

This second round addresses claims of the sole patent asserted in the second-filed action, *i.e.* the ’099 Patent.<sup>2</sup> The parties dispute the construction of the following two terms:

1. “[A] Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs” (’099 Patent, Claim 1); and
2. “[C]haracterized by an X-Ray spectrum with characteristic 2theta values” (’099 Patent, Claim 1).

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<sup>1</sup> All exhibits are attached to the accompanying declaration of April E. Weisbruch.

<sup>2</sup> The second-filed action (Civil Action No. 23-13764) was filed on August 31, 2023, and consolidated into this action on September 27, 2023. ECF No. 170.

*Markman* Opinion I governs construction of the first term. The Court ruled that the specifications of the '915, '257, and '415 Patents limit the open-ended language of the claims to rifaximin polymorphic mixtures which contain rifaximin  $\alpha$  and  $\beta$  polymorphs and no other rifaximin polymorphs. Ex. 1 at 45–72. The specification of the '099 Patent is substantively identical to the specifications of the '915, '257, and '415 Patents. *See* Ex. 2 ('099 Patent); Ex 3 ('915 Patent); Ex 4 ('415 Patent); Ex. 5 ('257 Patent). The ruling in *Markman* Opinion I – a ruling of law based solely on intrinsic evidence – is the law of the case. Thus, consistent with *Markman* Opinion I, this term should be construed to mean “a rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs and no other Rifaximin polymorphs.”

The second term was not addressed in *Markman* Opinion I. However, where, as here, a patentee has chosen to claim a composition using a particular set of x-ray diffraction peaks, the Federal Circuit and courts in this District have held that each of the peaks constitutes an independent limitation. Accordingly, the second disputed term should be construed as “having an X-ray spectrum with peaks at each of the recited 2theta values.”

## **II. LEGAL STANDARD**

The legal standard governing claim construction is set out in *Markman* Opinion I, Ex. 1 at 8–11, and is incorporated herein by reference.

### III. TECHNICAL BACKGROUND

The technical background for the '099 Patent is the same as for the patents asserted in the first round of claim construction. It is set out in *Markman* Opinion I, *id.* at 2–4, and is incorporated herein by reference.

### IV. THE '099 PATENT

Like the '915, '415, and '257 Patents, the '099 Patent is entitled “Polymorphic Mixture of Rifaximin and Its Use for the Preparation of Solid Formulations.” The '099 Patent is part of the same patent family as the '915, '415, and '257 Patents. The '915 Patent is the parent, the '257 Patent is a continuation of '915 Patent, the '415 Patent is a divisional of the '915 Patent, and the '099 Patent is a divisional of the '257 Patent. Ex. 1 (*Markman* Opinion I) at n.1; Ex. 2 ('099 Patent) at Cover Page. The four patents share a substantively identical specification.

Like the other patents in this family, the '099 Patent is directed to “[a] Rifaximin polymorphic mixture of  $\alpha/\beta$  form in a relative ratio of 85/15 $\pm$ 3 and a process for its preparation.” *E.g.*, Ex.2 ('099 Patent) at Abstract. Also like the other patents, the '099 Patent claims the “Rifaximin polymorphic mixture” by reference to a specific set of 18 x-ray diffraction peaks.

During prosecution of the '099 Patent, the applicant initially amended claims 33 and 34 to recite the below (presented in ‘clean’ form):

33. A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs in a  $\alpha/\beta$  relative ratio of  $85/15 \pm 3$ .

34. The tablet of claim 33, wherein the Rifaximin polymorphic mixture is characterized by an X-ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

Ex. 6, CURIFAX\_0085870–CURIFAX\_0085873 (Amendment and Response to Restriction Requirement dated February 1, 2023) at CURIFAX\_0085871.

Subsequently, the Examiner rejected then-pending Claim 33 under 35 U.S.C. § 103 as obvious over three references: Viscomi *et al.* (US20120059023, ‘Viscomi’), Jahagirdar *et al.* (EP2420226, ‘Jahagirdar I’), and Jahagirdar *et al.* (EP2011486, ‘Jahagirdar II’). Ex. 7, CURIFAX\_0085876–0085893 (Non-Final Office Action dated March 2, 2023) at CURIFAX\_0085880. As to Claim 34, the Examiner stated that it “would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.” *Id.* at CURIFAX\_0085878.

In response, the applicant canceled claim 34 and incorporated the limitations into Claim 33 as shown below:

33. (Currently Amended) A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs in a  $\alpha/\beta$  relative ratio of  $85/15 \pm 3$ ,

wherein the Rifaximin polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32,

5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

Ex. 8, CURIFAX\_0086007–0086011 (Amendment dated March 16, 2023); *id.* at CURIFAX\_0086010 (“The rejection of claims 33 and 36-48 under 35 U.S.C. § 103 for obviousness over [Viscomi, Jahagirdar I, and Jahagirdar II] is respectfully traversed in view of the above amendments incorporating the limitations of claim 34, which was not rejected for obviousness over [these references], into claim 33.”).

Based on the amendment and applicants’ argument, the Examiner issued a Notice of Allowability, explaining that the prior art, particularly the Viscomi reference, “does not specifically teach a Rifaximin polymorphic mixture of  $\alpha/\beta$  form in a relative ratio of  $85/15 \pm 3$ , characterized by an X-Ray spectrum with characteristic 2theta values as recited in claim 33. *These are specific peaks that are not disclosed in Viscomi and the other references.*” Ex. 9, CURIFAX\_0086026–CURIFAX\_0086029 (Notice of Allowability dated March 24, 2023) at CURIFAX\_0086027 (emphasis added).

## **V. PERSON OF ORDINARY SKILL IN THE ART**

A person of ordinary skill in the art would have been a multi-disciplinary team including: (1) a person who would have had a Ph.D. in chemistry, chemical engineering, or a related discipline, with a minimum of three years’ experience related to powder x-ray diffraction analysis of solid active pharmaceutical ingredients (“API”) and/or drug products, along with other forms of characterization,

testing, and/or evaluation of API and/or drug products; (2) a person who would have had a Ph.D. in chemistry, chemical engineering, pharmacology, or a related discipline with knowledge and/or experience related to the manufacture of solid active pharmaceutical ingredients and the manufacture of drug products; (3) a person who would have had a Ph.D. in chemistry, chemical engineering, pharmacology, biology, molecular biology, or a related discipline with knowledge and/or experience with respect to solid polymorphic forms of chemical compounds, specifically including rifaximin, along with their characterization, testing, properties, and *in vivo* operation; and (4) a person that would have had (i) a Ph.D. in pharmacology, biology, molecular biology, biomedical science, microbiology, or a related discipline, and/or (ii) a medical degree and board certification in gastroenterology. For each of these disciplines, a POSA team member could have a bachelor's and/or master's degree along with longer relevant experience.

## VI. ARGUMENT

### A. “[A] Rifaximin polymorphic mixture that comprises $\alpha$ and $\beta$ Rifaximin polymorphs” (’099 Patent, Claim 1)

Curia’s Proposed Construction	Defendants’ Proposed Construction
Construction of “a Rifaximin polymorphic mixture that comprises $\alpha$ and $\beta$ Rifaximin polymorphs” is not necessary. To the extent construction is necessary, “a Rifaximin polymorphic mixture that comprises $\alpha$ and $\beta$ Rifaximin polymorphs” is meant to have its plain and ordinary meaning,	“A rifaximin polymorphic mixture that comprises $\alpha$ and $\beta$ Rifaximin polymorphs and no other Rifaximin polymorphs”

e.g., “any Rifaximin polymorphic mixture that comprises both the $\alpha$ and $\beta$ forms of Rifaximin.” The term “comprises” is open ended and its plain and ordinary meaning allows for inclusion of other rifaximin polymorphs.	
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Claim 1 of the '099 patent recites:

1. A tablet obtained by a dry granulation and tableting procedure comprising ***a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs*** in a  $\alpha/\beta$  relative ratio of  $85/15 \pm 3$ ,

wherein the Rifaximin polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

Ex. 2 ('099 Patent) Claim 1.

As discussed below, *Markman* Opinion I is the law of the case. Consistent with *Markman* Opinion I, the term “a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs” should be construed to mean “a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs and no other Rifaximin polymorphs.”

The Court ruled in *Markman* Opinion I that similar open-ended claim language from the '915, '257 and '415 Patents is properly construed to mean rifaximin polymorphic mixtures that contain the  $\alpha$  and  $\beta$  rifaximin polymorphs and no other rifaximin polymorphs.

This included “a rifaximin polymorphic mixture in  $\alpha/\beta$  form” in Claim 1 of the ’915 Patent and Claim 1 of the ’257 Patent. The Court found “that though the claim language, standing on its own, *leaves open the possibility that the disputed terms may encompass additional rifaximin polymorphs*, the claim language, when read in view of the specifications, indicate that the proper construction of ‘[a] rifaximin polymorphic mixture of  $\alpha/\beta$  form’ is one that contains no other rifaximin polymorphs.” *Id.* at 46 (emphasis added). The Court held that “the specifications of the ’915 Patent and ’257 Patent are affirmatively limiting,” *id.* at 53, and “preclude [the] possibility” that other rifaximin polymorphs could be present, *id.* at 54. Thus, the Court found the claim language was open-ended but held “the specifications indicate that the proper construction of ‘[a] rifaximin polymorphic mixture of  $\alpha/\beta$  form’ is one that contains no other rifaximin polymorphs.” *Id.* at 49. The Court found this construction confirmed by the prosecution history. *Id.* at 54.

The Court applied the same analysis to claims that use the term “comprises,” as in the current disputed term of Claim 1 of the ’099 Patent. Thus, for example, the Court found that “[a] pharmaceutical composition” in the phrase “[a] pharmaceutical composition *comprising* the polymorphic mixture of Rifaximin of claim 1,” Ex. 3 (’915 Patent) Claim 2; Ex. 5 (’257 Patent) Claim 2, was limited to “a pharmaceutical composition comprising a rifaximin polymorphic mixture of  $\alpha/\beta$  form and no other rifaximin polymorphs,” rejecting Plaintiff’s argument that “[b]y using the terms

‘comprising’ and ‘mixture’” the claims “do not exclude additional elements from the polymorphic mixture of Rifaximin.” Ex. 1 at 63.

Similarly, the Court found that “[a] tablet, **comprising** the Rifaximin polymorphic mixture of Claim 1” means “[a] tablet, comprising the Rifaximin polymorphic mixture of Claim 1 and no other rifaximin polymorphs,” again rejecting the argument that use of the term “comprising” in the claim language meant that additional rifaximin polymorphs could be present. *Id.* at 64–66 (emphasis added). The Court ruled that for the same reasons set out in its discussion of “a rifaximin polymorphic mixture of  $\alpha/\beta$  form” – namely that the specifications are “affirmatively limiting” – the proper construction of “[a] tablet, comprising the Rifaximin polymorphic mixture of Claim 1” is one that contains no other rifaximin polymorphs. *Id.* at 66.

In addition, the Court construed “a pharmaceutical composition” in the phrase “a pharmaceutical composition **comprising** a therapeutically effective amount of Rifaximin in an  $\alpha/\beta$  polymorphic mixture,” Ex. 4 (’415 Patent) Claims 1 and 9, to mean “a pharmaceutical composition comprising a rifaximin polymorphic mixture of  $\alpha/\beta$  form and no other rifaximin polymorphs,” Ex. 1 at 66–70. Noting that “the ’415 Patent specification is substantially the same as the ’915 and ’257 Patent specifications, *id.* at 67, the Court held “the specification confirms that the claimed pharmaceutical composition comprises a rifaximin polymorphic mixture of  $\alpha/\beta$  form

and no other rifaximin polymorphs,” *id.* at 69. The Court reached this conclusion “based on the prosecution history of the ‘915 Patent, which is relevant in construing terms in the ‘415 Patent – a member of the same patent family.” *Id.* at 69 n.15 (citing *Capital Mach. Co. v. Miller Veneers, Inc.*, 524 Fed. App’x 644, 649 (Fed. Cir. 2013)).

Finally, the Court also construed “the pharmaceutical composition **comprises** 550 mg of Rifaximin  $\alpha/\beta$  mixture,” Ex. 4 (‘415 Patent) Claims 4 and 12, to mean “the pharmaceutical composition comprises 550 mg of Rifaximin  $\alpha/\beta$  mixture and no other rifaximin polymorphs,” again rejecting the argument that the use of the term “comprises” in the claim language means that other rifaximin polymorphs can be present, Ex. 1 at 70–72.<sup>3</sup>

Claim 1 of the ‘099 Patent includes similar language to the above-cited claims of the ‘915, ‘257 and ‘415 Patents. In each instance, the claim language is open ended. The Court expressly found that “a rifaximin polymorphic mixture in  $\alpha/\beta$  form,” Ex. 3 (‘915 Patent) Claim 1; Ex. 5 (‘257 Patent) Claim 1, is open ended, Ex. 1 at 46, while the language of the other four terms includes the term “comprising,” which is well established to be open-ended transitional term. *Invotrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003); Ex. 1 at 19-20 (finding

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<sup>3</sup> Based on the Court’s construction of these claims in *Markman* Opinion I, Plaintiff stipulated to non-infringement of the ‘915, ‘257, and ‘415 Patents and dismissal of all claims related thereto. ECF No. 226.

Claim 1 of '355 Patent, which includes “comprising,” to be open-ended and rejecting the argument it would be necessary “to recite the term ‘comprising’ twice for the claim to properly be construed as open-ended”); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371–72 (Fed. Cir. 2005). Notwithstanding the presence of the term “comprising,” in each instance the Court held that the specifications are “affirmatively limiting” and that the claims are limited to mixtures or compositions that contain the  $\alpha$  and  $\beta$  rifaximin polymorphs and no other rifaximin polymorphs.

Here, the previously-construed term “[a] tablet, **comprising** the Rifaximin polymorphic mixture of claim 1,” Ex. 3 ('915 Patent) Claim 3; Ex. 5 ('257 Patent) Claim 10, is highly similar to the term currently in dispute, namely “a tablet . . . that **comprises** a Rifaximin polymorphic mixture that **comprises**  $\alpha$  and  $\beta$  Rifaximin polymorphs.” Ex. 2 ('099 Patent) at Claim 1. The only difference between the two is that Claim 1 of the '099 Patent adds another “comprises” term. But the above-quoted tablet claims of the '915 and '257 Patents already contain the open-ended term “comprising.” Adding an additional “comprising” does not make the claim term any more open-ended. Ex. 1 (*Markman* Opinion I) at 19-20. Here, as with each of the other “comprising” or “mixture” claims in this patent family, the Court ruled the claims are limited to mixtures or compositions that contain the  $\alpha$  and  $\beta$  rifaximin polymorphs and no other rifaximin polymorphs.

There was good reason for the Court's rulings in *Markman* Opinion I. After discussing various disclosures in the specification, the Court wrote:

These passages of the specification, which explain that the conversion between polymorphic forms of rifaximin was a problem in the prior art, repeatedly emphasize that it is critical to guarantee the consistency of crystalline forms because of regulatory requirements in the drug industry and because different crystal forms of rifaximin exhibit different pharmaceutical properties, disparage prior art processes that did not result in the '*desired  $\alpha$  or  $\alpha/\beta$  mixtures*' but rather resulted in '*the undesired  $\gamma$  polymorphic form or other polymorphic mixtures,*' and attribute the '*surprising[]* properties of the inventions to the fact that an  $\alpha/\beta$  mixture in a relative ratio of 85/15 $\pm$ 3 can be prepared *consistently*, indicate that Claim 1 of the '915 Patent and Claim 1 of the '257 Patent do not encompass polymorphs other than the desired and consistently produced  $\alpha/\beta$  forms in a specific ratio. This conclusion is further supported by the fact that the summaries of the inventions state that '[i]t has now *surprisingly* been found that a new Rifaximin form, *consisting of  $\alpha/\beta$  mixture in a relative ratio of 85/15 $\pm$ 3 can be prepared consistently[,]* solving the problems of the prior art as discussed above,' namely that the consistency and conversion between polymorphic forms of rifaximin was a problem.

Ex. 1 at 51-52 (original emphasis, citations omitted). In sum, the Court concluded that "the specifications of the '915 Patent and '257 Patent are affirmatively limiting," noting that analogous facts in the Federal Circuit's decision in *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296 (Fed. Cir. 2011), are "instructive on this point." *Id.* at 53. The Court also found the prosecution history of the '915 Patent further confirms its ruling. *Id.* at 54. Moreover, the Court rebutted Plaintiff's contrary arguments at length, carefully addressing and rejecting each of Plaintiff's arguments. *Id.* at 55-62.

The Court's ruling in *Markman* Opinion I that the specifications of the '915, '257 and '415 Patents "affirmatively limit[]" the open-ended claim language of these patents to compositions and mixtures containing the  $\alpha$  and  $\beta$  rifaximin polymorphs and no other rifaximin polymorphs is the law of the case and governs here. *See Tundo v. Passaic Cty.*, 2018 WL 734663, at \*5 (D.N.J. Feb. 6, 2018) (Salas, J.) ("The law of the case doctrine directs courts to refrain from re-deciding issues that were resolved earlier in the litigation." (quoting *Pub. Interest Research Grp. Of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116 (3d Cir. 1997))). The law of the case doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case. This rule of practice promotes the finality and efficiency of the judicial process by protecting against the agitation of settled issues." *Rastelli Partners, LLC v. Baker*, 2024 WL 1739739, at \*4 (D.N.J. Apr. 23, 2024) (quoting *In re Continental Airlines, Inc.*, 279 F.3d 226, 233 (3d Cir. 2002)).<sup>4</sup>

Thus, the ruling from *Markman* Opinion I should be applied to the construction of "a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs" in Claim 1 of the '099 Patent, a patent in the same family as those

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<sup>4</sup> The Court's holdings in *Markman* Opinion I on the above-cited terms of the '915, '257, and '415 Patents are rulings of law as they are based solely on intrinsic evidence. *See Teva Pharms., USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015) (claim construction based solely on intrinsic evidence is a question of law); *Corephotonics, Ltd. v. Apple, Inc.*, 84 F.4th 990, 1003 (Fed. Cir. 2023) (same).

addressed in *Markman* Opinion I, such that this term is construed to mean “a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs and no other Rifaximin polymorphs.”

Moreover, even if the law of the case doctrine were not applied, the Court’s analysis of the intrinsic record in *Markman* Opinion I is decisive and compels the conclusion that this term should be given Defendants’ proposed construction.

Finally, it bears noting that ten days prior to the Court’s issuance of *Markman* Opinion I, Plaintiff argued in a January 16, 2024 letter to the Court, ECF No. 206, that no claim construction was necessary for the ’099 Patent and that the terms of the ’099 Patent Defendants had proposed for construction (the subject of the instant claim construction briefing) should be given the same construction the Court would give to the counterpart claim terms from the ’915, ’257, and ’415 Patents when it issued its claim construction decision. Ex. 10 at 3.

Plaintiff wrote it “believes that the claim terms Defendants currently propose for construction were briefed and sufficiently argued in the previous phase of claim construction in this case . . . As these claim terms are from patents in the same family as the patent the current claim terms derive, ***the Court should construe them in the same way.***” *Id.* (emphasis added). Plaintiff argued that “a Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs,” Ex. 2 (’099 Patent) Claim 1, should be given the same construction the Court would give to “[a] Rifaximin

polymorphic mixture of  $\alpha/\beta$  form,” Ex. 3 (’915 Patent) Claim 1; Ex. 5 (’257 Patent) Claim 1, and that no claim construction for the ’099 Patent was necessary. Ex. 10 at 3.

Plaintiff’s candid admission in the January 16, 2024 letter to the Court that these claim terms should be construed “in the same way” — contrary to its position after seeing *Markman* Opinion I — further confirms the conclusion that the Court’s analysis in *Markman* Opinion I applies and the term should be construed as Defendants propose.

**B. “characterized by an X-Ray spectrum with characteristic 2theta values” (’099 Patent, Claim 1)**

Curia’s Proposed Construction	Defendants’ Proposed Construction
Read in the context of the claim and specification as a whole, this phrase means: “characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.”	“having an X-ray spectrum with peaks at each of the recited 2theta values”

Claim 1 of the ’099 Patent recites:

1. A tablet obtained by a dry granulation and tableting procedure comprising  $\alpha$  Rifaximin polymorphic mixture that comprises  $\alpha$  and  $\beta$  Rifaximin polymorphs in a  $\alpha/\beta$  relative ratio of  $85/15 \pm 3$ ,

wherein the Rifaximin polymorphic mixture is ***characterized by an X-Ray spectrum with characteristic 2theta values*** at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

Ex. 2.

Defendants propose that the emphasized language above be given the following construction: “having an X-ray spectrum with peaks at each of the recited 2theta values.”

The language of the claim is clear and unambiguous. The claim recites that the Rifaximin polymorphic mixture is characterized by an x-ray spectrum with 18 specific peaks (“recited 2theta values”). When a patentee has chosen to claim a composition by using a particular set of peaks, each of the listed peaks is an independent claim limitation and all must be present to establish infringement. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1566 (Fed. Cir. 1997) (holding each peak is an independent limitation, and “in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims”); *In re Sebela Patent Litig.*, 2017 WL 3449054, at \*15 (D.N.J. Aug. 11, 2017) (“[W]here a patentee claims a compound by reference to a set of IR peaks, each of those peaks constitutes an independent limitation that must be met in order to show infringement.” (citing *Glaxo*, 110 F.3d at 1564-66)); *see also Cephalon, Inc. v. Sun Pharm.*, 2012 WL 12904999, at \*10–11 (D.N.J. Dec. 20, 2012) (relying on *Glaxo* and treating individual XRPD peaks as claim limitations); *Abbot Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 775 (N.D. Ill. 2007) (treating individual XRPD peaks as claim limitations).

As noted in *In re Sebel*, “[a]lthough there may be multiple sets of correct peaks that can be selected to characterize a spectrum, a patentee who chooses to claim a compound using a particular set of 18 peaks, for whatever reasons, should be held to that list.” 2017 WL 3449054, at \*15. Following this reasoning, the court in *AstraZeneca AB v. Andrx Labs, LLC*, construed “characterized by the following major peaks in its X-ray diffractogram” to mean “having each of the referenced major peaks in its X-ray powder diffractogram with normal experimental error.” 2017 WL 111928, at \*47 (D.N.J. Jan. 11, 2017).

Based on *Glaxo* and the above-cited cases, “characterized by an X-Ray spectrum with characteristic 2theta values” is properly construed to mean “having an X-ray spectrum with peaks at each of the recited 2theta values.”

Defendants’ proposed construction is further supported by the prosecution history. During prosecution, to overcome the prior art, the claim was amended at direction of the Examiner to incorporate the specific set of 18 XRPD peaks now recited in Claim 1 of the ’099 Patent. Ex. 8, CURIFAX\_0086007–0086011 (Amendment dated March 16, 2023). After the amendment, the Examiner explained the claims were allowable because the prior art did not “specifically teach a Rifaximin polymorphic mixture of  $\alpha/\beta$  form . . . characterized by an X-ray spectrum with characteristic 2theta values as recited” in the claim. The Examiner went on to state: “*These are specific peaks that are not disclosed in Viscomi and the other*

*references.*” Ex. 9, CURIFAX\_0086026–CURIFAX\_0086029 (Notice of Allowability dated March 24, 2023) at CURIFAX\_0086027 (emphasis added).

The fact that this specific set of 18 XRPD peaks was added to overcome the prior art and expressly identified by the Examiner as the reason for allowance over Viscomi reinforces the conclusion that the claim is properly construed as “having an X-ray spectrum with peaks at each of the recited 2theta values.”

Accordingly, “characterized by an X-Ray spectrum with characteristic 2theta values” should be construed to mean “having an X-ray spectrum with peaks at each of the recited 2theta values.”<sup>5</sup>

## VII. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court adopt Defendants’ proposed constructions.

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<sup>5</sup> For clarity, under Defendants’ proposed construction, each of the “recited 2theta values” is modified by the term “about,” as recited in Claim 1 of the ’099 Patent (“characterized by an X-ray spectrum with characteristic 2 theta values at *about* . . .”). In other words, the “recited 2theta values” incorporate and are modified by the term “about,” which by the language and structure of the claim applies to each of the recited 2theta values. In this respect, Claim 1 of the ’099 Patent is different from the claims of the ’915, ’257, and ’415 Patents, which do not expressly recite the word “about.” In construing the claims of the ’915, ’257, and ’415 Patents, the Court read the unrecited term “about” into the claims as a matter of construction but declined to further define the term. Ex. 1 (*Markman* Opinion I) at 110. While Defendants respectfully contend that the term “about” recited in Claim 1 of the ’099 Patent requires construction, Defendants recognize that the Court’s ruling not to further define “about” in *Markman* Opinion I is the law of the case and governs here.

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Respectfully submitted,

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